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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/080,504	02/22/2002	Olaf Reinhold	38466.00008.UTL	8672
36183 7590 02/06/2008 PAUL, HASTINGS, JANOFSKY & WALKER LLP 875 15th Street, NW Washington, DC 20005			EXAMINER MITCHELL, TEENA KAY	
			ART UNIT 3771	PAPER NUMBER
			MAIL DATE 02/06/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/080,504	Applicant(s) REINHOLD ET AL.	
	Examiner Teena Mitchell	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-84 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-84 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is responsive to the amendment filed on 10/2/07. As directed by the amendment, claims 1, 21, 23, 25, 43, 63, 65, and 67 have been amended and no claims have been cancelled nor added. Thus, claims 1-84 are presently pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-84 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. While applicant has support in the originally filed specification for the limitation of, "...The system 2 may also be connected to the housing by suspension-like attachments..." the originally filed specification does not provide support for the newly added limitations of, "...a suspension attachment..." in claims 1, 21, 23, 25, 43, 63, 65, and 67. Such limitations would constitute new matter as suspension-like is not the same as suspension attachment.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

Art Unit: 3771

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-19, 21-61 and 63-84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens ('934) in view of Voges ('841).

Regarding claim 1, Stevens discloses a device (fig. 6-7) for delivering an aerosolized compound, comprising: a medicament reservoir (30,31); a housing 1 having an upstream end and a down stream end and comprising an inlet 3 and an outlet between which is formed an airflow path wherein the inlet is located at the upstream end of the housing and facing opposite to the outlet (fig. 7), except for a system comprising an entry port and an element to generate particles of a desired size for physical ejection through apertures from an ejection head. However, Voges teaches a device (fig. 2) for delivering an aerosolized compound (e.g. nicotine at col.5, line 58), the device comprising: a reservoir (10) that stores the compound; a system comprising an entry port (12) and an element to generate particles of a desired size for physical ejection through one or more apertures (15) from an ejection head (14) of the element, wherein said particles comprise a compound (e.g. nicotine at col.5, line 58), and wherein said system is fluidly connected (11) to a reservoir (10); and a housing (2,3) comprising an inlet (7) and an outlet (5) between which is formed an airflow path (see bold arrows in fig. 2 extending from outside of housing 2,3 through inlet 7 and through outlet 5) and in which at least the ejection head is disposed in the air flow path (i.e. as illustrated in fig.2) downstream of the inlet (7) and upstream from the outlet (5), wherein the housing

provides for a substantially unobstructed airflow between the ejection head and the outlet when air traverses the airflow path from the inlet to the outlet. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention was made to modify the device in the Stevens' reference, to include a system having all the features as discussed above, as suggested and taught by Vogues, for the purpose of providing a droplet ejection system that could issue a predetermined number of discrete droplets of the medication as desired (see abstract). As to the a suspension attachment connecting the system to the housing such that the airflow is substantially unobstructed when between the system and the housing (both Stevens note Fig. 6, 7, element 30 is suspended between the channel via the shape of the ends air is able to flow between the system and housing via the apertures in element (30); Voges teaches a suspension attachment (note Figs. 4, 5; the system is between two ends of the housing (i.e., suspended) and air flows between the system and housing via apertures 7)) therefore Stevens and Voges are readable upon the newly added limitations.

Regarding claims 2 and 3, Voges teaches that the compound (col. 5, line 58) is a pharmaceutical compound and is stored in the reservoir (10) in a liquid formulation (col. 5, line 58 discloses nicotine dissolved in water).

Regarding claims 4-8, Voges (col. 9, line 53 - col.10, line 21) discloses a variety of suitable drugs for delivery by the device. These drugs include proteins and hormones (e.g. corticosteroids and antidiuretic hormone), and small molecules (e.g. budesonide) as well as other drugs that are fully capable of being gene delivery vehicles; and the

Art Unit: 3771

reservoir (10) and particle generating system (14,15) in Voges (fig.2) are illustrated as being located within housing (2,3).

Regarding claims 9-14, Voges teaches that the housing (fig. 2) is aerodynamically shaped (e.g. cylindrically shaped thereby providing for easy flow of air there through and around); the reservoir (10) is being detachable (col. 6, lines 37-40); the reservoir (10) and particle generating system (11,12,14,15) is illustrated (e.g. in fig.2) as being integrated into a single unit; the particle generating system is an electronic ejection device (col. 6, lines 45-51); the electronic ejection device uses heat (20 and col. 6, lines 26-30) to generate particles ejected from the ejection head; the electronic ejection device includes a piezoelectric component (col.10, lines 52-54) to generate particles ejected from the ejection head.

Regarding claims 15-17, Voges discloses the desire particle size is one that allows particles to transit to and be deposited in alveoli (col.9, lines 37-47). That is, Voges recognizes that particles having a diameter less than 5 microns are preferred because particles of this size range will follow respiratory passages. One of ordinary skill would recognize respiratory passages to include alveoli.

Regarding claim 18, fig. 2 of Voges illustrates substantially unobstructed airflow being substantially laminar prior to exiting the housing outlet (5).

Regarding claim 19, fig. 2 of Voges illustrates substantially unobstructed airflow comprises a substantially homogeneous mixture of ejected compound and air from inlet (7) prior to exiting the housing outlet (5).

Regarding claims 21-24 are substantially equivalent in scope to claims 1 and 18 and are included in Stevens as modified by Vogues for the reasons set forth above with respect to claims 1 and 18.

Regarding claims 25-42 are substantially equivalent in scope to claims 1-19 and are included in Stevens as modified by Vogues for the reasons set forth above with respect to claims 1-19. Voges as discussed above also discloses a digitally controlled electronic ejection (col.6, lines 45-51) of aerosolized medicament.

The balance of the claims 43-61, 63-84, are substantially equivalent in scope to claims 1-19, 21-42 and are included in Stevens as modified by Vogues for the reasons set forth above with respect to claims 1-19, 21-42.

Claims 20 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over of Stevens ('934) in view Voges ('841) as applied to claims 1-19,21-61,63-84 above, and further in view of Gonzalez ('614). The combined references disclose all the claimed features except for an inner surface of the housing is proximal to the ejection head and extending to the outlet is contoured to minimize turbulence. Gonzalez, in a device for delivering an aerosolized compound (page 1, col.2, lines 100+), teaches an inner surface of the housing is proximal to the aerosol generation system and extending to the outlet is contoured (A' to a2 to e2 of fig.1). The contouring of the inner surface of the housing of Gonzalez would implicitly cause variations in the flow rate and flow pattern of the aerosol being formed as it passes there through (e.g. smaller diameter portions would cause increased flow rate and more laminar flow whereas increased diameter portions would cause decreased flow rate and relatively more turbulent flow. It

would have been obvious to further modify the inner surface of the housing proximal to the ejection head to make it contoured because it would have provided a means for controlling the flow rate and flow pattern of the aerosol being formed as taught by Gonzalez. Claim 62 is substantially equivalent in scope to claim 20 and is included in Stevens/Voges as further modified by Gonzalez for the reasons set forth above with respect to claim 20.

Response to Arguments

Applicant's arguments filed 10/02/07 have been fully considered but they are not persuasive. Applicant argues that Stevens and Voges are neither one readable upon the newly added limitations of, "...a suspension attachment..." based upon the system being located between two end of the housing, the system is therefore suspended via an attachment (in the reference of Stevens note Figs. 6, 7, element 30 rest on ledge of (2)), note rejection above. The examiner is maintaining the previous examiners rejection because the newly added limitations are not patentably distinct over the Stevens/Voges references as noted above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teena Mitchell whose telephone number is (571) 272-4798. The examiner can normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3771

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Teena Mitchell/

Primary Examiner, Art Unit 3771

February 4, 2008